

K162418 Pioneer Plus CatheterDec 2, 2016
94 days to decisionK162418 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k162418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 30, 2016
Decision date	Dec 2, 2016
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Volcano
Location	San Diego, CA, US
Contact	MARY STANNERS
510(k) history	2 submissions · 2 cleared · 2016-2017

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